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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,001	06/16/2000	Elfi Biedermann	69176	2626

22242 7590 07/30/2002

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/596,001

Applicant(s)

BIEDERMANN ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 12, 14, 24, and 32-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49 is/are allowed.
- 6) ☒ Claim(s) 2-8, 12, 14, 24, 32-48, and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's amendment of 5-6-02 has been considered. While the previous rejection of 112/2nd has been overcome, the amended and new claims introduce new matter. Thus, new ground of rejection is presented herein along with the previous 112/1st and 102(b) rejections.

With claims 1, 9-11, 13, 15-23, and 25-31 cancelled, claims 2-8, 12, 14, 24, remain pending along with new claims 32-50.

Claim Rejections - 35 USC § 112

1. **New Matter:** Claims 2-7, 12, 14, 24, 32, 40-43, 46-48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Said claims recite a proviso for G that has no support in the instant disclosure. Note, even in the claims, G never represents $-(CH_2)_{ma}-CH-(R^{10a})-(R^{11a})$.

Claims 4-7, 14, 24, 40-43, 46-48 and 50 are rejected under 35 U.S.C. 112/1st paragraph because they depend on claims 2, 3, 12, and 32.

2. **New Matter:** Claims 35-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The methods of preparation recited in claims 35-39 do not have support or description in the specification.

3. **Scope of Enablement:** Claims 33, 34, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of solid tumors of colon, lung and leukemia, does not reasonably provide enablement for inhibiting tumor growth in other part of the body, and suppressing autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is maintained for reasons stated previously. Although there is support for tumors of colon, lung, and leukemia, said guidance does not sufficiently allow the skilled oncologist to treat other tumors with the same compounds. Likewise, there is no guidance to use the claimed compounds in suppressing autoimmune diseases. It would even be contradicting with the treatment of leukemia for one skilled in the art to suppress autoimmune diseases. Thus, it would require undue experimentation for one skilled in the art to find a dosage that could treat leukemia while suppressing autoimmune diseases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 2-8, 12, 14, 24, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

- a. **Nishikawa et. al.** (J. Med. Chem.): See compounds #18a, 18b on page 585.
- b. **Nishikawa et. al.** (EP'782) : See compounds #7, 11, and 22 in Table 5.
- c. **Haeck et. al.** (EP'045) : See compound #1 on page 11; also the process in Example IV.

The rejection is maintained for the reasons stated previously. The proviso excludes the situation where both R¹³ and R¹⁴ represent phenyl groups, but fails to exclude the situation where R¹³ and R¹⁵ can both be phenyl groups. Thus, said references still anticipate the instant claims.

Allowable Subject Matter

5. Claim 49 is allowed. The prior arts of record do not teach a method of inhibiting colon, lung, liver, and leukemia tumor cell growth using compounds claimed herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

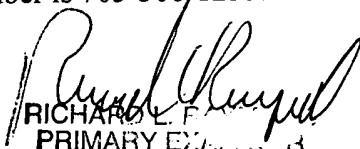
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


RICHARD L. F. MUKUND SHAH
PRIMARY EXAMINER
ART UNIT 1624
Mukund Shah
Supervisory Patent Examiner
Art Unit 1624



T. Truong

July 26, 2002